

REMARKS

This is in response to the Office Action dated 10/16/09.

Claims 1-14, 16, and 18-33 are pending. Claims 3-14 have been withdrawn from consideration.

Claims 1 and 16 have been amended to address the claim objection raised by the Examiner.

35 USC 103 Rejection

Claims 1-2, 16, and 18-33 were rejected as allegedly being obvious over Krieg et al. (US 2003/0139364) in view of Brown et al. (US 5,573,781) and Granger (WO 1996-029394). Applicants respectfully traverse and request reconsideration.

The Office Action acknowledges that “Krieg et al. does not disclose resiquimod for treatment of breast cancer as a preferred embodiment or depositing within the cancer tissue.”

Brown teaches administering a cytostatic agent intra-tumorly, but does not teach resiquimod (or any other compound that is a TLR 7/8 agonist having a mechanism like resiquimod).

Granger teaches administration of lymphocytes with a tumor, but also does not teach resiquimod or other TLR 7/8 agonists.

Applicants maintain that one skilled in the art would not have been motivated or had any reasonable expectation of success that resiquimod injected in depot formulation would be effective. Resiquimod is not a direct cytostatic agent, as in Brown. It does not have direct anti-tumor activity, but works indirectly by activating the TLR 7/8 receptors on certain immune system cells and thereby enhances immune response to recognize and destroy cancerous cells. However, many cancers have a microenvironment that effectively evades the immune system

and one skilled in the art would have had no basis based on Brown or Krieg (or Granger) to believe that injecting a depot formulation of resiquimod into a tumor mass would be effective. Granger actually requires the injection of immune system cells into a tumor, but does not teach the injection any drug that stimulates the immune response like resiquimod or suggest that such approach would work.

Applicants respectfully submit that since neither Brown nor Granger teach or suggest resiquimod or any compound with a TLR 7/8 mechanism like resiquimod, one skilled in the art would have had no basis whatsoever for a reasonable expectation of success of the claimed invention, particularly when one considers the challenging immune system evading microenvironment within tumors.

Applicants respectfully request withdrawal of the rejection.

In view of the above, it is submitted that the application is in condition for allowance. Examination and reconsideration of the application as amended are requested.

Applicant requests a telephone interview to more fully understand the Examiner's position and advance this case to issuance.

Respectfully submitted,

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Date

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